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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/629,309	07/29/2003	J. R. Patil	U 014742-0	6603

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EXAMINER	
KOSSON, ROSANNE	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 07/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/629,309	PATIL ET AL.	
	Examiner	Art Unit	
	Rosanne Kosson	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 June 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4/14/04, p. 3*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

5-0-0

DETAILED ACTION

The amendment filed on June 10, 2005 has been received and entered. No claims have been amended. Claims 1-19 have been canceled, and claims 20-25 have been added. Accordingly, claims 20-25 are examined on the merits herewith.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Biological Deposit

In the previous Office action, Applicants were requested to supply information as to whether or not a biological deposit of *A. junii* SC14 was made and, if so, whether or not this deposit complied with the conditions of the Budapest treaty. No information was provided, and this requirement is still outstanding.

Claim Rejections - 35 USC § 112

Claims 20-25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, claim 20 recites a bioemulsifier from any *Acinetobacter* strain isolated from human skin that retains 35% stability after

140 hours at 10°C. Claim 21 recites a bioemulsifier from any *Acinetobacter junii* that has this same property.

But, the specification discloses a bioemulsifier isolated from only one organism, *Acinetobacter junii* SC14 (NCIM 5150), hereinafter referred to as "SC14." No other bioemulsifiers are disclosed. There is no evidence that any other representative species of such a large and varied genus- bioemulsifiers from other *Acinetobacter* species or from other organisms in the species of *junii*- were in the possession of the inventors at the time of filing. With respect to the property of stability recited in claim 20, as discussed below, that is a characteristic whose presence or absence may be determined only after each bioemulsifier is purified and an emulsion having a particular ratio of oil or fat to water and a particular composition of the oily and aqueous phases is prepared. It does not describe the bioemulsifier, particularly as the term "35% stability" is unclear (see below). For example, does 65% of the emulsion separate or does 65% of the bioemulsifier decompose?

To satisfy the written description aspect of 35 U.S.C. 112, first paragraph, for a claimed genus of molecules, it must be clear that: (1) the identifying characteristics of the claimed molecules have been disclosed, e.g., structure, physical and/or chemical characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or a combination of these; and (2) a representative number of species within the genus must be disclosed. Because the specification discloses only one *Acinetobacter* bioemulsifier, the claims fail to satisfy the written description requirement.

Applicants' arguments regarding the written description rejection in the previous Office action have been considered, but they are not persuasive of error. Because claims 1-6 have been replaced by claims 20-25, the rejection has been modified correspondingly. Applicants assert that claim 1 meets the written description requirement because there is a description of bioemulsifiers comprising proteins, polysaccharides and lipid in the specification. But, as noted previously, Applicants have described a bioemulsifier from only one organism, SC14. They have indicated the percentages of protein, polysaccharide and lipid, but have not studied or analyzed the molecular composition beyond this finding. Applicants note that on p. 7, lines 7-8, of the specification, species of dermal *Acinetobacter* are described. These lines, however, cite references discussing *A. calcoaceticus* RAG-1 and its emulsifier Emulsan. The source of this bacterium is not clear from the specification, and descriptions of dermal *Acinetobacter* species are not present.

Claims 20-25 are also rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a bioemulsifier from SC14, does not reasonably provide enablement for a bioemulsifier from any *Acinetobacter* strain isolated from human skin that retains 35% stability after 140 hours at 10°C. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

As a result, the scope of the instant claims is not commensurate with the enablement of the instant disclosure, because practice of the claimed invention would require undue experimentation by an artisan of ordinary skill in the art to isolate bioemulsifiers from a number of different dermal *Acinetobacter* species and strains and determine which bioemulsifiers have the property of 35% stability after 140 hours at 10°C. Undue experimentation would also be required to determine whether stability refers to the percentage of the emulsion on a volume basis that remains in one phase or whether stability refers to the chemical composition remaining intact. Undue experimentation would also be required to test emulsions of many different ratios of oily composition to aqueous composition and many different oils or fats mixed with water or buffer to determine whether or not the resulting emulsion may be considered to have 35% stability. The specification does not include any procedures or systematic methods that would provide an indication of the stability properties of a bioemulsifier isolated from dermal *Acinetobacters*. Further, different bioemulsifiers from different *Acinetobacter* isolates are likely to vary biochemically, because of the genetic and metabolic heterogeneity among species and strains of *Acinetobacter*. See Juni, "Interspecies transformation of *Acinetobacter*: genetic evidence for a ubiquitous genus," J Bacteriol 112:917-929, 1972, which discloses that *Acinetobacter* strains differ in their genetic make-up (GC content of their genomes and phenotype), ability to use glucose as a carbon source, ability to use other sugars as a carbon source, ability to transform other *Acinetobacter* auxotrophs, and in their synthesis of enzymes such as oxidases and nitrate reductases (see pp. 925, 920 and 923). See also Bouvet et al., "Taxonomy of

the genus *Acinetobacter* with recognition of *A. baumannii* sp. nov., *A. haemolyticus* sp. nov., *A. johnsonii* sp. nov., and *Ac. junii* sp. nov. and amended descriptions of *A. calcoaceticus* and *A. lwoffii*," Int J of Systematic Bacteriol 36:226-240, 1986, which also discloses the heterogeneity of *Acinetobacter*, grouping them into a large number of genospecies. *A. junii*, in genospecies 5, appear in Tables 4, 7, 8 (see pp. 233, 235 and 236). Thus, bioemulsifiers isolated from two different dermal *Acinetobacters* or two different strains of *A. junii* may be the same or different with respect to composition, stability, enzymatic properties and rheological properties.

The factors to be considered in determining whether undue experimentation is required are summarized In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). The court in Wands states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' " (Wands, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary (immense, because Applicants disclose only one *Acinetobacter* bioemulsifier and claim any emulsifier from a dermal *Acinetobacter* that has 35% stability after 140 hours at 10°C), (2) the amount of direction or guidance

presented (guidance is presented for only one dermal *Acinetobacter*, SC14), (3) the presence or absence of working examples (working examples are provided for only SC14), (4) the nature of the invention (one bioemulsifier isolated from one bacterium), (5) the state of the prior art (many species and strains of *Acinetobacter* are known and at least some of these are known to produce an emulsifier, but the physical and biochemical properties, biochemical content and enzymatic properties are not often specified in the literature), (6) the relative skill of those in the art (very high, that of highly trained research scientist), (7) the predictability or unpredictability of the art (see below), and (8) the breadth of the claims (broad, as discussed above).

With respect to the quantity of experimentation necessary, to demonstrate that any emulsifier from an *Acinetobacter* isolated from human skin has 35% stability after 140 hours at 10°C, many experiments would have to be conducted. Emulsifiers would have to be isolated from a large number of *Acinetobacter* and from a large number of *A. junii* strains. Many sets of emulsions would have to be prepared with each emulsifier, each set containing a different fat or oil, and each sample in each set having a different ratio of oil or fat to water or buffer. Each sample would have to be analyzed after 140 hours at 10°C and its stability determined, either the percentage remaining emulsified or the percentage of the emulsifier remaining intact. This large amount of experimentation is necessary, because Applicants disclose one emulsifier from a dermal *Acinetobacter* with a particular stability property but claim any emulsifier from dermal *Acinetobacter* with this property. The data from these experiments is required to fill in the gap. The gap in information is especially large, as the 35% stability may be defined in various

ways, as discussed above and below, and as different humans with different skin types and living in different parts of the world have many different strains of *Acinetobacter* and *A. junii* on their skin. The emulsifying properties of each of these species and strains may or may not be the same as Applicants' claimed composition.

To be commensurate in scope with a broad claim for any emulsifier from a dermal *Acinetobacter* having 35% stability, a great deal of guidance must be present in the specification to enable one of skill in the art to identify, prepare and analyze these bioemulsifiers. As noted above, only one bioemulsifier is disclosed.

Regarding predictability, *Acinetobacter* and *A. junii* strains are genetically heterogeneous, as discussed above. As a result, it cannot be predicted whether or not the emulsifiers from any two of these organisms would be the same or different, especially with respect to 35% stability, which is an ambiguous term.

Accordingly, claims 20-25 fail to satisfy the enablement requirement.

Applicants' arguments regarding the enablement rejection in the previous Office action have been considered, but they are not persuasive of error. This rejection has been modified in accordance with the amended claims. Applicants assert that claims 1-6 are enabled because the specification provides a procedure for producing and testing an emulsifier from a dermal *Acinetobacter*. But, as noted above, the procedure describes how to isolate and test an emulsifier from only one bacterium, SC14. No systematic methods or guidelines are provided for isolating other emulsifiers from dermal *Acinetobacter* with the same physical, biochemical or enzymatic properties.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 20-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, claim 20 recites a bioemulsifier that retains 35% stability after 140 hours at 10°C. As discussed above, it cannot be determined if 35% stability refers to the percentage of an emulsion that remains in one phase or the percentage of the emulsifier that remains intact without decomposing. Additionally, the ratio of oil or fat to water in the emulsion that has 35% stability and the nature of the oily phase and the aqueous phase are not defined. Consequently, the metes and bounds of the claims are indefinite.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 20-25 rejected under 35 U.S.C. 103(a) as being unpatentable over Gutnik et al. (US 4,230,801); Shabtai et al. ("Emulsan: a case study of microbial capsules as industrial products," Symposium: Extracellular Microbial Polysaccharides, chap. 19, pp. 291-307, publication date not provided); and Zosim et al. (Biotechnology and Bioengineering 24:281-292, 1982) in view of Pola Kasei Kogyo KK (JP 53-148543).

Gutnik discloses a bioemulsifier produced by *Acinetobacter* (species not specified) comprising protein, polysaccharide and lipid. The lipid content by weight varies from 2 – 19%, depending on the carbon source selected for the growth medium. Upon deproteinization of the emulsans, all of the emulsifying activity was found to remain with the emulsans, which are the lipoacyl heteropolysaccharide component of the bioemulsifier (see col. 4, lines 21-48, and col. 4, line 67, to line 5). With regard to the stability of the emulsions made with the bioemulsifier, the stability was found to depend on the ratio of oil to emulsifier, but at ratios of less than 25, over 24 hours at 25°C was required for a breakdown of greater than 50% (see col. 27, line 42, to col. 28, line 8). Gutnik I does not identify the protein component of the bioemulsifier or specify the ratio of protein:polysaccharide:lipid. Gutnik I also does not specify the amount of the protein that remains in the cells that produce the bioemulsifier vs. the amount

secreted from the cells. Further, Gutnik I does not disclose using the bioemulsifier to reduce the viscosity of almond oil or the stability of the bioemulsifier at 10°C. But, the bioemulsifier of Gutnik appears to be the same as Applicants' claimed bioemulsifier, as the Office does not have the facilities and resources to provide the factual evidence needed in order to establish that the composition of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is on Applicants to prove that the claimed product is different from those taught by the prior art and to establish patentable differences. See In re Best 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989).

Shabtai discloses that *Acinetobacter calcoaceticus* RAG-1 has a heteropolysaccharide capsule containing a protein (an esterase) and emulsan (a potent bioemulsifier). The esterase was found to destabilize the capsule to permit release of the emulsan. The esterase is released from the cells concurrently with the release of the emulsan from the cells. After about 6 hours in culture, more than half the esterase, as measured by enzyme activity, is in the cell-bound fraction, while less than half the esterase is in the culture medium (see Abstract, pp. 295-297). These esterase properties appear to be the same as those in Applicants' bioemulsifier. As discussed above, the Office does not have the ability to test whether or not the bioemulsifier of Shabtai is the same or different than Applicants' bioemulsifier.

Neither Gutnik I nor Shabtai disclose the ratio of protein:polysaccharide:lipid in the bioemulsifier, but the ratio may be the same or different than Applicants' ratio. But,

because Shabtai discloses that the amounts of protein and lipopolysaccharide produced by and secreted by *Acinetobacter* vary with culture time and culture medium, it would have been a matter of routine optimization on the part of the artisan of ordinary skill to grow the organism in a fermentor and harvest the fermentation medium or the cell mass in the fermentor at any desired time to obtain a bioemulsifier with the desired ratios of protein, polysaccharide and lipid, such as the ratios in Applicants' claimed invention.

Further with respect to the stability of the emulsions produced by the bioemulsifier of Gutnik, Zosim discloses that the emulsions may have a stability of 50% or better over a period of 40 hours at 25°C and that the rate of decrease in stability after 40 hours is slow (see pp. 284-285). Although the stability of the bioemulsifier at 10°C was not measured, one of ordinary skill in the art would have expected with a reasonable degree of success that the bioemulsifier from *Acinetobacter*, as disclosed by Zosim, would have shown significant stability after 140 hours at 10°C and that this stability would depend on the ratio of oil to water and the chemical composition of the oil.

Pola Kasei Kogyo discloses that when castor oil is treated with an esterase, the viscosity of the oil decreases (see English abstract). One of ordinary skill in the art would have recognized that when an oil such as almond oil was treated with an esterase, such as the esterase contained in the claimed bioemulsifier, the viscosity of the almond oil would have decreased. The skilled artisan, therefore, would have expected a decrease in the viscosity of the oil upon treatment with an esterase-containing bioemulsifier, as well as larger decreases in viscosity when larger amounts of

esterase are used in the treatment. Similarly to the foregoing, it is not disclosed whether or not the bioemulsifiers in the cited references have the property of reducing the viscosity of almond oil that is found in Applicants' bioemulsifier. This is another property that the Office cannot test for comparison to the prior art. Nevertheless, one of ordinary skill in the art would reasonably expect that two bioemulsifiers containing a similar amount of esterase would be able to reduce the viscosity of almond oil to a similar degree.

In view of the foregoing, a holding of obviousness is required. No claim is allowed.

Applicants' amendments necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rosanne Kosson whose telephone number is 571-272-2923. The examiner can normally be reached on Monday-Friday, 8:30-6:00, with alternate Mondays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Rosanne Kosson
Examiner
Art Unit 1653

rk/2005-07-21